

Amendment and Response

Applicant: Laurent Schaller

Serial No.: 09/828,322

Filed: April 5, 2001

Docket No.: P0021814.00 / M190.319.101

Title: BRIDGE CLIP TISSUE CONNECTOR APPARATUS AND METHODS

REMARKS

This is responsive to the Final Office Action mailed April 18, 2008 and in support of the concurrently-filed Request for Continued Examination. In that Office Action, claim 1 was rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Claims 1-6, 20, 24-26, 39-43, 47-50, 54, and 55 were rejected under 35 U.S.C. §102(b) as being anticipated by Sander, U.S. Patent No. 5,374,268 ("Sander"). Claims 44 and 51 were rejected under 35 U.S.C. §103(a) as being unpatentable over Sander.

The Examiner's indication that claims 31-38 have been allowed is noted with appreciation.

Additionally, the Examiner's indication that claims 7-19, 21-23, 45, 46, 52, and 53, although objected to, would be deemed allowable if rewritten in independent form, is also noted with appreciation.

With this Response, claims 1, 3, 20, 24, 41, 48, and 55 have been amended. Claims 1-26 and 31-55 remain pending in the application and are presented for reconsideration and allowance.

35 U.S.C. §112, First Paragraph, Rejections

In rejecting claim 1 under 35 U.S.C. §112, first paragraph, the Office Action contends that the subject matter "at least one of the two clips is a self-closing clip" was not described in the specification. Applicant disagrees. For example, claims 5 and 20 as filed recite the language in question. Withdrawal of the rejection under §112, first paragraph, is requested.

35 U.S.C. §§102, 103 Rejections

In rejecting various ones of the independent claims, the Office Action characterizes Sander as teaching a "self-closing" clip by referencing the language at column 4, lines 60-67 that states "as the needles are pushed through the meniscus to draw the edges of the tear together". As a starting point, the Office Action identifies the anchor members 14 of Sander as being the claimed "clips". The needles 12 are separable from the anchor members 14. Thus, any inference

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from the cited language has no bearing on the claims; regardless of whether the needles 12 somehow achieve a “closed” relationship relative to tissue, no such disclosure exists relative to the anchor members 14. That is to say, to the extent the anchor members 14 are applied as the claimed clips, Sander does not disclose the anchor members/clips 14 as being “self-closing”.

In addition, the term “self-closing” inherently entails a closed-type arrangement within which tissue is held. Further, “self-closing” requires that the clip in and of itself accomplishes the closed configuration. In contrast, as a straight (or curved) needle is pushed through tissue, the needle does not in and of itself close or hold the tissue. Instead, the needle remains straight and thus is not a “closing” device. Further, the “drawing” of tissue together with the needles 12 of Sander requires an action by the surgeon (i.e., the pushing force); in the absence of this surgeon-applied action, the tissue would not be drawn together. Thus, the needles 12 of Sander are clearly not “self-closing”.

Independent Claim 1

With the above in mind, claim 1 recites that at least one of the two clips is a self-closing clip. As described above, the anchor members 14 (referenced in the Office Action as being the “clips” of claim 1) are not sized and shaped to attach tissues and hold the tissues together therein, nor are they self-closing clips. The needles 12 similarly do not satisfy the language of claim 1. In addition, claim 1 has been amended to recite that the self-closing clip is adapted to self-transition from a first shape to a second shape, with the first and second shapes being different. Sander does not teach or reasonably make obvious this additional feature. Nothing in Sander teaches the anchor members 14 as having a first shape and a second shape, let alone the anchor members 14 being adapted to self-transition from a first shape to a different, second shape. Further, although the Office Action does not apply the needles 12 as being the “clips” of claim 1, it is noted that the disclosed needles do not provide different shapes, let alone are they adapted to self-transition from a first shape to a different second shape. As a point of reference, it is noted that in FIG. 1, the needles 12 are straight, and in the alternative embodiment of FIG. 2, the needles 32 are curved. Sander makes clear that the embodiments of FIGS. 1 and 2 are different.

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That is to say, the needles 12 are always straight or the needles 32 are always curved; in no instance does Sander describe the needles as self-transitioning between different shapes.

For at least the above reasons, then, it is respectfully submitted that claim 1 is allowable over the cited art.

Claims 2-19, 39, and 40 depend from claim 1 and thus are allowable. Additional distinctions exist. For example, amended claim 3 recites that each of the two clips has an open configuration and a closed configuration independent of the other clip. In rejecting claim 3, the Office Action asserts that a position of the anchoring members 14 relative to one another constitutes the open configuration and closed configuration as claimed. As clarified, however, amended claim 3 provides that the clips in and of themselves have an open configuration and a closed configuration. Thus, movement of the anchor members 14 relative to one another according to Sander has no relevancy to the language of claim 3. Thus, amended claim 3 recites additional allowable subject matter.

Dependent claim 4 recites that the bridge portion provides a predetermined spacing between the clips. In rejecting claim 4, the Office Action references the suture 16 of Sander as being the claimed “bridge,” and that FIG. 4 teaches the suture/bridge 16 as providing a predetermined spacing. Applicant respectfully disagrees. The spacing of FIG. 4 is dictated mainly by the tissue within which the needles 12 have been inserted. In the absence of the holding force provided by the surrounding tissue, a “predetermined spacing” between the anchor members 14 would not exist; that is to say, because the suture 16 is flexible, it is impossible for the suture 16 to be a bridge portion that provides a predetermined spacing as claimed. Thus, claim 4 recites additionally allowable subject matter.

Dependent claim 6 recites that the self-closing clip comprises shape memory material. In rejecting claim 6, the Office Action states that “the bridge portion is flexible and therefore has shape memory material”. Applicant disagrees that the suture/bridge 16 of Sander has shape memory material. Regardless, the flexibility and alleged shape memory of the suture/bridge portion 16 is irrelevant to the language of claim 6. Claim 6 states that the self-closing clip

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comprises shape memory material; the “bridge” of Sander has no bearing on the self-closing clip as claimed. Thus, claim 6 recites additionally allowable subject matter.

Independent Claim 20

Independent claim 20 recites a surgical fastener including at least one self-closing clip. As described above, the anchor members 14 (otherwise asserted by the Examiner as being the “clips” of claim 20) are not self-closing, nor do they provide a closed configuration as claimed. Further, claim 20 has been amended to provide that the closed configuration is an unbiased configuration having a loop shape, and the open configuration is a biased configuration having a shape differing from a shape of the closed configuration. Nothing in Sander teaches the anchor members 14 as having a loop shape in a closed configuration, let alone a biased configuration having a shape differing from a shape of the closed configuration. Further, though not referenced in the Office Action as being the “clips” of claim 20, the needles 12, 32 of Sander are either curved or straight, and do not provide both a loop shape and a different shape. Finally, claim 20 recites a release mechanism having a first position biasing the clip in the open configuration, and a second position to unbias a clip into the closed configuration. The Office Action references the suture/bridge 16 as being the “release mechanism” as claimed. Applicant disagrees. The suture 16 does not have a position that unbias the anchor members/clips 14 into a closed configuration having a loop shape as claimed, nor a first position that biases the anchor members/clips 14 into the open configuration having a shape differing from a shape of the closed configuration.

For at least the above reasons, amended claim 20 is allowable over Sander.

Independent Claim 24

Independent claim 24 recites a surgical fastener including at least one self-closing clip. As described above, the anchor members 14 of Sander are not self-closing clips, nor are the needles 12, 32. Notably, claim 24 recites that tissue piercing members are releasably coupled to ends of the claimed surgical fastener, necessitating that the needles 12 or 32 of Sander cannot be

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interpreted as the “clips” of claim 24. In addition, claim 24 has been amended to recite that the self-closing clip has a loop shape terminating at the first end (to which the first tissue piercing member is releasably coupled). The anchor members 14 of Sander do not have a loop shape, and thus do not teach or reasonably make obvious the features of amended claim 24. For at least the above reasons, then, amended claim 24 is allowable over the cited art.

Claims 25 and 26 depend from claim 24 and thus are also allowable. Additional distinctions exist. For example, claim 25 recites a release mechanism that activates release of the piercing members from the surgical fastener. In rejecting claim 25, the Office Action references the suture 16 as being the claimed “release mechanism”. Applicant fails to understand how the suture 16 can be a mechanism that activates release of the needles 12 from the anchor members 14. To the extent the rejection of claim 25 is maintained, a more complete explanation is respectfully requested.

Independent Claim 41

Independent claim 41 relates to a tissue connector apparatus including an elongated member having first and second loop shaped portions each having a free end and being deformable into a second deformed shape. In rejecting claim 41, the Office Action references FIGS. 2 and 6 of Sander as teaching the looped and deformed shapes. In this regard, it is respectfully noted that FIGS. 2 and 6 are different embodiments. The needles 32 of FIG. 2 are not the needles 12 of FIG. 6. Thus, while the needles 32 may be curved in FIG. 2, nothing in Sander teaches that the needles 32 deform into a different state provided by the straight needles 12 of FIG. 6. In addition, claim 41 has been amended to recite that each loop shaped portion is self-tending to return from the second deformed shape towards the loop shape. Sander does not teach or reasonably make obvious at least this feature. Once again, the needles of Sander are either curved (i.e., the needles 32) or straight (i.e., the needles 12) but not both; relative to the curved needles 32, nothing in Sander teaches the needles 32 as being deformable into a deformed shape, let alone being self-tending to return from the deformed shape toward the curved shape.

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For at least the above reasons, claim 41 is allowable over Sander. Claims 42-47 depend from claim 41 and thus are allowable.

Independent Claim 48

Independent claim 48 relates to a tissue connector apparatus having first and second loop shaped portions each having a piercing element at one end and being deformable into a second deformed shape. As amended, claim 48 recites that the loop shaped portions have the property of tending to return towards its loop shape by moving upon itself. As described above, the curved needles 32 of FIG. 2 (relied upon by the Office Action in rejecting claim 48) are not deformable into a second deformed shape, nor do they have the property of tending to return toward the looped shape. Even further, the rigid, curved needle 32 clearly does not tend to return toward a loop shape by moving upon itself, as claimed. Thus, independent claim 48 is allowable over Sander.

Claims 49-54 depend from claim 48 and thus are allowable.

Independent Claim 55

Independent claim 55 relates to a tissue connector apparatus having two clips, with each clip self-transitioning from an open configuration to a closed configuration. As described above, the anchor members 14 (referenced in the Office Action as being the “clips” as claimed) do not provide both an open configuration and a closed configuration. Even further, the anchor members 14 do not and cannot self-transition from an open configuration to a closed configuration. Thus, amended claim 55 is allowable over Sander.

CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 1-26 and 31-55 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 1-26 and 31-55 are respectfully requested.

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No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 50-0471.

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

For the foregoing reasons, Applicant believes all the pending claims are in a condition for allowance and should be passed to issue. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to contact either Katrina Witschen at Telephone No. (763) 505-8418 or Timothy A. Czaja at Telephone No. (612) 573-2004.

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Respectfully submitted,

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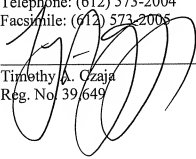
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